

**UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY**

OTSUKA PHARMACEUTICAL CO., LTD.,)	
)	
Plaintiff,)	
)	
v.)	
)	Civil Action No.:
INDOCO REMEDIES LIMITED and)	
HTERO LABS LIMITED,)	
)	
Defendants.)	
)	

COMPLAINT FOR PATENT INFRINGEMENT

Plaintiff Otsuka Pharmaceutical Co., Ltd. (“Otsuka”), by way of Complaint against Defendants Indoco Remedies Limited (“Indoco”) and Hetero Labs Limited (collectively, “Defendants”), alleges as follows:

THE PARTIES

1. Otsuka is a corporation organized and existing under the laws of Japan with its corporate headquarters at 2-9 Kanda Tsukasa-machi, Chiyoda-ku, Tokyo, 101-8535, Japan. Otsuka is engaged in the research, development, manufacture and sale of pharmaceutical products.

2. Upon information and belief, Indoco is a corporation organized and existing under the laws of India, having its principal place of business at L-32, 33, 34 Verna Industrial Area, Verna, GOA-4-3722, India.

3. Upon information and belief, Hetero Labs Limited is a corporation organized and existing under the laws of India, having its principal place of business at 7-2-A2, Hetero Corporate Industrial Estates, Sanath Nagar, Hyderabad - 500 018, Andhra Pradesh, India.

NATURE OF THE ACTION

4. This is an action for infringement of U.S. Patent No. 9,089,567 (“the ’567 patent”), arising under the United States patent laws, Title 35, United States Code, § 100 *et seq.*, including 35 U.S.C. §§ 271 and 281. This action relates to Indoco’s filing of an Abbreviated New Drug Application (“ANDA”) under Section 505(j) of the Federal Food, Drug and Cosmetic Act (“the Act”), 21 U.S.C. § 355(j), seeking U.S. Food and Drug Administration (“FDA”) approval to manufacture, use, import, sell and offer to sell generic pharmaceutical products (“Defendants’ generic products”) prior to the expiration of the asserted patent.

JURISDICTION AND VENUE

5. This Court has subject matter jurisdiction under 28 U.S.C. §§ 1331 and 1338(a).

6. This Court has jurisdiction over Indoco. Indoco is in the business of manufacturing, marketing, importing and selling pharmaceutical drug products, including generic drug products. Upon information and belief, Indoco, directly or through its wholly-owned subsidiaries, manufactures, imports, markets and sells generic drugs throughout the United States and in this judicial district. Upon information and belief, Indoco purposefully has conducted and continues to conduct business, directly or indirectly, in this judicial district, and this judicial district is a likely destination of Defendants’ generic products. According to its website, “Indoco . . . is a fully integrated, research-oriented global pharmaceutical company with a strong presence in 80 countries including USA & UK.” See <http://www.indoco.com/newsroom-pressrelease/press-release-anda-approval-18april-2013.pdf>.

And upon information and belief, “Indoco has 37 ANDAs at various stages” either under its own name or filed by partners, and “Indoco’s products are already available in the US market.” *See id.*

7. This Court has jurisdiction over Hetero Labs Limited. According to its website, “Hetero is the leading global supplier of APIs . . . to the pharmaceutical companies who manufacture formulations and new-generation products.” *See* <http://heteroworld.com/pages/business-api>. Upon information and belief, Hetero Labs Limited, directly or indirectly, manufactures, imports, markets and sells generic drugs throughout the United States and in this judicial district. Upon information and belief, Hetero Labs Limited maintains continuous and systemic contacts with New Jersey through its authorized U.S. agent, PharmaQ, Inc., located at Water View Plaza, 2001 Route 46, Suite 405, Parsippany, NJ 07054-1315.

8. Venue is proper in this judicial district under 28 U.S.C. §§ 1391(b) and (c), and § 1400(b).

FIRST COUNT FOR PATENT INFRINGEMENT

9. The U.S. Patent and Trademark Office (“PTO”) issued the ’567 patent on July 28, 2015, entitled “Method of Treating Cognitive Impairments and Schizophrenias.” A copy of the ’567 patent is attached as Exhibit A.

10. Otsuka is the owner of the ’567 patent by virtue of assignment.

11. The ’567 patent expires on January 28, 2022, subject to any supplemental patent term adjustment.

12. The ’567 patent is directed to and claims, *inter alia*, methods of treatment of schizophrenia.

13. Otsuka is the holder of New Drug Application (“NDA”) No. 21-436 for aripiprazole tablets, which the FDA approved on November 15, 2002.

14. Otsuka lists the ’567 patent in Approved Drug Products with Therapeutic Equivalence Evaluations (“the Orange Book”) for NDA No. 21-436.

15. Defendants have actual knowledge of the ’567 patent.

16. Otsuka markets aripiprazole tablets in the United States under the trademark Abilify®.

17. Upon information and belief, Indoco submitted ANDA No. 207397 to the FDA, under Section 505(j) of the Act, 21 U.S.C. § 355(j), seeking approval to manufacture, use, import, offer to sell and sell Defendants’ generic products in the United States.

18. Otsuka received a letter from Indoco dated November 23, 2015 (“Indoco’s 207397 letter”), purporting to include a Notice of Certification for ANDA No. 207397 under 21 U.S.C. § 355(j)(2)(B)(ii)(I) and 21 C.F.R. § 314.95 as to the ’567 patent.

19. Indoco’s 207397 letter alleges that the established name of the drug products that are the subject of Indoco’s ANDA is “aripiprazole 2, 5, 10, 15, 20 and 30 mg tablets.”

20. Upon information and belief, the manufacture, use, import, offer for sale and sale of Defendants’ generic products will, if approved and marketed, directly infringe at least one claim of the ’567 patent.

21. Upon information and belief, Defendants have taken active steps to intentionally induce infringement of the ’567 patent.

22. Upon information and belief, Defendants have taken active steps to encourage the sale and use of Defendants’ generic products by physicians, pharmacists and/or patients in accordance with the methods of treatment claimed in the ’567 patent by providing information

and instructions in Defendants' tablet package insert encouraging the use of aripiprazole in those methods of treatment.

23. Upon information and belief, under 35 U.S.C. § 271(e)(2)(A), Defendants have infringed at least one claim of the '567 patent by submitting, or causing to be submitted to the FDA, ANDA No. 207397 seeking approval to manufacture, use, import, offer to sell and sell Defendants' generic products before the expiration date of the '567 patent.

24. Upon information and belief, Indoco's actions relating to Indoco's ANDA No. 207397 complained of herein were done with the cooperation, participation, assistance, and for the benefit, of Indoco and Hetero Labs Limited.

WHEREFORE, Plaintiff Otsuka respectfully requests that the Court enter judgment in its favor and against Defendants on the patent infringement claims set forth above and respectfully requests that this Court:

- 1) enter judgment that, under 35 U.S.C. § 271(e)(2)(A), Defendants have infringed at least one claim of the '567 patent through Indoco's submission of ANDA No. 207397 to the FDA to obtain approval to manufacture, use, import, offer to sell and sell Defendants' generic products in the United States before the expiration of the '567 patent;
- 2) order that the effective date of any approval by the FDA of Defendants' generic products be a date that is not earlier than the expiration of the '567 patent, or such later date as the Court may determine;
- 3) enjoin Defendants from the manufacture, use, import, offer for sale and sale of Defendants' generic products until the expiration of the '567 patent, or such later date as the Court may determine;

- 4) enjoin Defendants and all persons acting in concert with Defendants, from seeking, obtaining or maintaining approval of Indoco's ANDA No. 207397 until expiration of the '567 patent;
- 5) declare this to be an exceptional case under 35 U.S.C. §§ 285 and 271(e)(4) and award Otsuka costs, expenses and disbursements in this action, including reasonable attorney fees; and
- 6) award Otsuka such further and additional relief as this Court deems just and proper.

Respectfully submitted,

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